

invention elected.” Applicants are still unclear what scope the Examiner considers to constitute the elected invention, and, therefore, would appreciate an indication of this in the next Office Action, if the application is not allowed.

The specification was objected to under 35 USC § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e., as failing to provide an enabling disclosure. The Examiner provides no explanation whatsoever why the application is considered to be deficient, and, therefore, has not discharged his clear initial burden to establish a *prima facie* case of nonenablement. In this regard, Applicants would remind the Examiner that the allegations in the specification must be accepted as true in the absence of reasonable doubts supported by sound technical reasoning or evidence. *In re Marzocchi et al.*, 169 USPQ 367, 369 (CCPA 1971). In the absence of reasonable doubts supported by sound technical reasoning or evidence, Applicants submit that the enablement must be accepted, and the Examiner must reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Claims 2 and 4-8 were rejected under 35 USC § 102(b) as being anticipated by Matsumura et al. (“Matsumura”), unidentified, but, apparently, *J. Jap. Oil. Chem. Soc.*, 40: 709-714 (1991), or *J. Am. Oil Chem. Soc.*, 67: 996-1001 (1990), Shoji et al. (“Shoji”), U.S. Patent No. 5,459,257, or Ikekawa et al. (“Ikekawa”), *Chem. Pharm. Bull.*, 35: 2894-2899 (1987). The

Examiner does not indicate what embodiments in any of these references are considered to be anticipatory. However, in response, Applicants would remind the Examiner that anticipation requires that each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference, and, further, if the Examiner relies on a theory of inherency as to any particular element, then the extrinsic evidence must make clear that such element is *necessarily* present in the thing described in the reference, and the presence of such element therein would be so recognized by persons skilled in the art. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Further, inherency is not established by probabilities or possibilities, and the mere fact that a property may result from a given circumstances is not sufficient; instead it must be shown that such property *necessarily* inheres in the thing described in the reference. *Id.* The rejected claims all previously required that the active substances be “[applied] to skin, hair and/or nails.” There does not appear to be any teaching of such topical applications to these particular body areas in any of the cited references, and, moreover, this fact is apparently recognized by the Examiner himself, as he concedes in connection with the obviousness rejection that “the primary references, differ as to: 1) the employment of these medicaments dermally or cosmetically.” In short, as the Examiner himself admits that the cited references do not teach all aspects of the present invention, Applicants request that the Examiner reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Claims 2-9 were rejected under 35 USC § 103(a) as being obvious over Matsumura, Shoji and Ikekawa in view of Ziolkowsky, *SOFW J.*, 121: 973-4, 976 and 979 (1995). As indicated above, the Examiner concedes that Matsumura, Shoji and Ikekawa do not teach the employment of Applicants' active ingredients dermally or cosmetically. The Examiner also concedes that these primary references do not teach the administration levels of these references for these purposes. In order to overcome these clear deficiencies of these primary references, the Examiner relies on Ziolkowsky, which, according to the Examiner "teaches the claimed compounds as useful for a dermal, cosmetic use." According to the Examiner, "[p]ossessing this teaching, the skilled artisan would have been motivated to employ the claimed compounds for the dermal, or cosmetic use herein claimed and enjoy a reasonable expectation of therapeutic success."

In response, Applicants submit that this combination of references does not make out a *prima facie* case. Where, as here, the claimed subject matter has been rejected over a combination of prior art references, a *prima facie* case of obviousness is only made out where the prior art would have (1) suggested to those of ordinary skill in the art that they should carry out the claimed process and also (2) revealed to those of ordinary skilled in the art that in so carrying out the claimed process, those of ordinary skill in the art would have had a reasonable expectation of success. *See, for example, In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). Applicants submit that both the suggestion and the reasonable expectation of success are lacking

here, the Examiner's statements notwithstanding.

While Ziolkowsky may have applied similar compounds to hair, there is not the slightest indication in the abstract upon which the Examiner relies that such application has been for the purpose of combating bacteria, fungi and/or viruses, as presently claimed. Consequently, the combination of Ziolkowsky and the primary references still leaves persons skilled in the art without a reasonable expectation that application of the substances of the primary references to hair to combat bacteria, fungi and/or viruses therein would have been successful. The fact that Ziolkowsky might have applied similar compounds to hair does not mean that all activities of such compounds could have been realized on hair.

Further, without a suggestion in these references that bacteria, fungi and/or viruses could be topically combated with the instant compounds with a reasonable expectation of success, persons skilled in the art would not have been motivated to determine proper administration levels for topical applications.

Respectfully, this combination of cited references does not make out a case that the claimed invention would have been *prima facie* obvious. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

Finally, Applicants point out that an information disclosure statement was filed on May 24, 1999, which cited the references on the international search report and included a completed Form 1449 for the Examiner to initial, thereby indicating the Examiner's consideration of the references cited in the information disclosure statement. The customary practice would have called for a copy of the initialed form to be returned to Applicants. However, to date, the copy of the initialed form has not been received. Therefore, Applicants respectfully request that the Examiner locate the form, and, if not already done, initial the form, and return a copy of the initialed form to Applicants along with the next Office Action or, hopefully, a Notice of Allowance. If the information disclosure statement and/or the Form 1449 is missing from the official file, then Applicants respectfully request that the Examiner telephone the undersigned at telephone number (212) 808-0700 so that a copy of the information disclosure statement and/or the Form 1449 can be provided to the Examiner on an expedited basis.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be

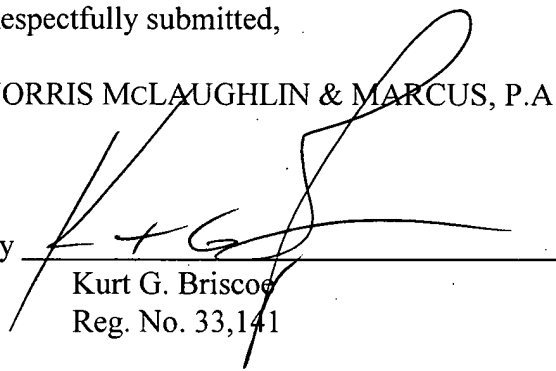
promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

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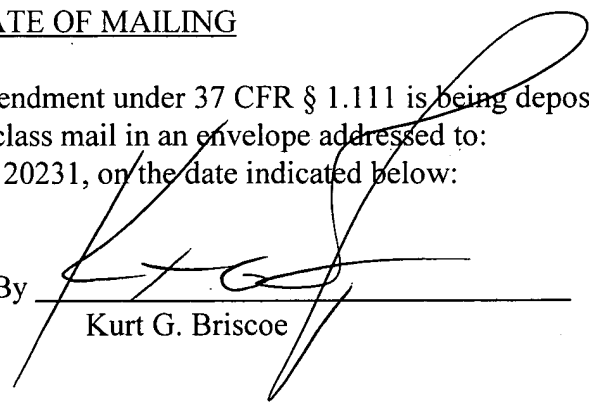
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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents, Washington, D.C. 20231, on the date indicated below:

Date: January 26, 2001

By


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